

### REMARKS

The Office action of May 14, 2003, has been carefully considered.

Double patenting rejections have been maintained over U.S. Patents Nos. 5,908,697 and 6,277,404. While Applicants believe that the present claims are not obvious in view of the claims of the prior patents, in order to advance prosecution, Applicants will file a terminal disclaimer to remove these rejections when claims of the present application are found to be otherwise in condition for allowance.

Claims 22 through 28, 32 through 34 and 40 through 41 have been rejected under 35 USC 102(b) as anticipated by CA 2133421.

Applicants have now amended Claims 22 and 41 in order to incorporate the subject matter of Claim 27 which has now been cancelled. Claims 22 and 41 now recite that the compound which is an active agent encapsulated within the vesicles is selected from the group consisting of reducing molecules, oxidizing and molecules sensitive to hydrolysis.

Claim 22 has also been amended to recite the method for preparation of the composition, these method steps previously having been incorporated in Claims 33, 35 and 41. The purpose of incorporation of these method steps is to clearly distinguish the claimed multilamellar vesicles from vesicles of the prior art.

The Canadian patent has been cited to show multilamellar vesicles of the claimed type, incorporating a polymer to reinforce their rigidity and either hydrophobic or hydrophilic active agents. The rejection has been maintained on the basis that the claims are composition claims, and the reference teaches polymers which may be present in the present claims.

The Canadian patent does not, however, disclose vesicles

containing an active agent selected from the group consisting of reducing molecules, oxidizing molecules and molecules sensitive to hydrolysis, and a stabilizing agent which is an inhibitor of the chemical degradation of the active agent. There is certainly no disclosure or suggestion that the polyacrylamide polymer of the Canadian reference is an inhibitor of chemical degradation for the above cited molecules.

The same arguments apply as well to Claims 33 and 41, both of which are directed to preventing the chemical degradation of oxidizing molecules, reducing molecules and molecules sensitive to hydrolysis.

Withdrawal of this rejection is requested.

Claims 22 through 31, 33 through 34 and 40 through 41 have been rejected under 35 USC 102(b) as anticipated by WO 96/31194.

The Office action has taken the position that the claims do not distinguish over the prior art on the basis that the instant claim language does not distinguish the product over the prior art multilamellar vesicles. It is noted, however, that Claims 22, 33 and 41 all incorporate the method steps for preparing the vesicles of the invention, and that these method steps result in vesicles which cannot be and are not prepared according to WO 96/31194. Applicants have thus described these vesicles both structurally and in product-by-process terms, and it is submitted that the result are vesicles which are clearly different from those disclosed in the prior art. Withdrawal of this rejection is accordingly requested.

Claims 22 through 27 and 33 through 41 have been rejected under 35 USC 102 as anticipated by Munechika.

Once again, it is noted that the vesicles of Munechika are classical liposomes, and not the vesicles of the

invention, which have been described both in structural terms and product-by-process terms. Thus, the product and method of the claimed invention cannot be disclosed by Munechika, and withdrawal of this rejection is requested.

Claims 22 through 41 have been rejected under 35 USC 103(a) over CA 2133421 or WO 95/18601 in view of Munechika.

As noted, only the Canadian patent is directed to vesicles of the type which are presently claimed. Munechika does disclose incorporating stabilizers in liposomes, but the stabilizers with the exception of tocopherol are all physical stabilizers for the liposomes.

Munechika specifically discloses that tocopherol is used for stabilizing the lipid, and not for stabilizing a specific active ingredient in the liposomes, and there is no disclosure or suggestion that the active ingredient in the molecule is a reducing molecule an oxidizing molecule or a molecule sensitive to hydrolysis which would need to be stabilized. With regard to Claim 35, there is no disclosure or suggestion that the tocopherol or any of the other stabilizers acts specifically as chemical stabilizers for the enzyme incorporated in the liposomes. While albumin, as has been pointed out in the Office action, may otherwise be known as a stabilizer for certain enzymes, this is not disclosed by Munechika, and in any event, Applicants do not claim the use of stabilizers of any sort in the liposomes disclosed by Munechika, but rather in a different type of liposome completely.

Withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicants submit that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,  
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